K093297

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epocal

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k-093297.

Summary Prepared: June 07, 2010

Submitted by:
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Contact:
Roy Layer
Director of Quality Assurance and Regulatory Affairs.

5.1 Identification of the Device

Device Name:	Acid, Lactic, Enzymatic Method
Proprietary / Trade Name:	epoc Lactate Test
Common Name:	Lactate acid test system
Classification Name:	Acid, Lactic, Enzymatic Method
Device Classification:	I (Class II with limitation of exemption)
Regulation Number:	862.1450
Panel:	Clinical Chemistry
Product Code:	KHP

5.2 Identification of the Predicate Device

i-Stat™ Lactate Test using i-Stat™ Model 300 Portable Clinical Analyzer

5.3 Description of the New Device

The epoc Lactate Test is being added as an additional sensor to the existing single use test card that is used with the epoc Blood Analysis System. This test card is inserted into the epoc Reader and all analytical steps are performed automatically. Patient and user information may be entered into the mobile computing device (epoc Host) during the automated analysis cycle.

The epoc Blood Analysis System is an in vitro analytical system comprising a network of one or more epoc Readers designed to be used at the point of care (POC). The readers accept an epoc single use test card containing a group of sensors that perform diagnostic testing on whole blood. The blood test results are transmitted wirelessly to an epoc Host, which displays and stores the test results.

The epoc System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of whole blood.

The test card panel configuration currently includes sensors for Sodium Na, Potassium K, Ionized Calcium iCa, pH, pCO_2, pO_2, Glucose and Hematocrit Hct. This submission adds Lactate (Lact) to this list of approved tests.

To perform a blood test, a new test card is inserted into a card reader's card slot with white label face down. When fully inserted, the test card is automatically engaged in the reader.

The card insertion process:

- Brings the cards sensor module into contact with the reader's electrical contact array;
- Brings the card's measurement region, which is the fluidic channel above the sensor array, into thermal contact with the reader's heater assembly for heating the measurement region to 37°C;
- Actuates the opening of the fluidic valve in the card and causes delivery of calibrator fluid from the reservoir to the measurement region.

After calibration, and upon a prompt by the reader (LED visual and audio beep), the user introduces a blood sample for measurement through the blood sample port to the card's measurement region. When sensors are contacted by the blood sample they generate electrical signals proportional to analyte concentrations in the blood sample, which are transmitted wirelessly by the Reader to the epoc Host. The epoc Host displays and stores the blood test results.

Changes to the epoc Blood Analysis System required to introduce the Lactate test include:

- Developing a new Lactate sensor and adding it to the existing epoc test card, which was already designed to accommodate additional sensors;
- Modifications to the existing EpocHost software application to accommodate the new test;
- Labeling changes including indications for use for the Lactate test.

5.4 Comparison of Technological Characteristics To Predicate Device

	epoc Blood Analysis System	**i-STAT Model 300**	
510(k) #	To be determined	K001387	**Same / Different**
Item	Device	Predicate	
Intended use	The Lactate test as part of epoc Blood Analysis System is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood using the BGEM (Blood Gas Electrolyte and Metabolytes) test card panels.	The i-STAT Model 300 Portable Clinical Analyzer is intended to be used by trained medical professionals for use with i-STAT test cartridges. i-STAT cartridges comprise a variety of clinical chemistry tests and test panels.	same
Where used	hospital	hospital	same

Measured parameters	pH, pCO_2, pO_2, Na, K, iCa, Hct, Gluc, Lact			pH, pCO_2, pO_2, Na, K, iCa, Hct, Gluc, Lact		same
Calculated parameters	TCO_2, HCO_3,BE,sO_2,Hgb			TCO_2, HCO_3,BE,sO_2,Hgb		same
Sample type	Venous, arterial and capillary whole blood			Venous, arterial and capillary whole blood		same
Reportable ranges	pH	6.5 - 8.0	pH units	pH	6.5 - 8.2	pH units	different
	pCO_2	5 - 250	mm Hg	pCO_2	5 - 130	mm Hg	different
	pO_2	5 - 750	mm Hg	pO_2	5 - 800	mm Hg	same
	Na	85 - 180	mmol/L	Na	100 - 180	mmol/L	different
	K	1.5 - 12	mmol/L	K	2.0 - 9.0	mmol/L	different
	iCa	0.25 - 4	mmol/L	iCa	0.25 - 2.5	mmol/L	different
	Hct	10 - 75	%PCV	Hct	10 - 75	%PCV	same
	Gluc	20 - 700	mg/dL	Gluc	20 - 700	mg/dL	same
	Lact	0.3 - 20	mmol/L	Lact	0.3 - 20	mmol/L	same
	TCO_2	1 - 85	mmol/L	TCO_2	5 - 50	mmol/L	different
	HCO_3	1 - 85	mmol/L	HCO_3	1 - 85	mmol/L	same
	BE_{ecf}	-30 - +30	mmol/L	BE_{ecf}	-30 - +30	mmol/L	same
	BE_b	-30 - +30	mmol/L	BE_b	-30 - +30	mmol/L	same
	sO_2	0 - 100	%	sO_2	0 - 100	%	same
	Hb	3.3 - 25	g/dL	Hb	3 - 26	g/dL	same
Sample volume	Non-volumetric over 95 µL			100µL			same
Test card	Unit-use card with - on-board calibrator in sealed reservoir - an electrochemical multi-sensor array - port for sample introduction - fluid waste chamber			Unit-use cartridge with - on-board calibrator in sealed reservoir - an electrochemical multi-sensor array - port for sample introduction - fluid waste chamber			same
Test card storage	Room temperature until expiry date			Fridge storage until expiry date including max 2 weeks at room temperature			different
Sensor array	A laminated foil sensor module			A micro-fabricated chip-set			different
Tests/sensor components	pH - PVC ion selective electrode pCO2 - QH modified Severinghaus type pO2 – membrane coated gold cathode Na - PVC ion selective electrode K - PVC ion selective electrode iCa - PVC ion selective electrode Glu - glucose oxidase based amperometric peroxide detection Lact - lactate oxidase based amperometric peroxide detection Hct – conductivity, gold electrodes			pH - PVC ion selective electrode pCO2 - QH modified Severinghaus type pO2 – membrane coated gold cathode Na - PVC ion selective electrode K - PVC ion selective electrode iCa - PVC ion selective electrode Glu - glucose oxidase based amperometric peroxide detection Lact - lactate oxidase based amperometric peroxide detection Hct – conductivity, gold electrodes			same same same same same same same same same
Analyzer components	Two housings; 1 - The reader comprising - Orifice for test card introduction - electrical connector to card - heater for 37°C operation - mechanical card engagement device for o making electrical contact to card's sensors o for rupture of calibrator reservoir o moving calibrator to sensors o engaging heaters with card - op-amp sensor signal detectors - iQC monitoring devices - Thermal controllers			A single housing comprising - Orifice for test card introduction - electrical connector to card - heater for 37°C operation - mechanical card engagement device for o making electrical contact to card's sensors o for rupture of calibrator reservoir o moving calibrator to sensors o engaging heaters with card - op-amp sensor signal detectors - iQC monitoring devices - Thermal controllers			different same same same same same same same same same

	- MUX - A/D - Bluetooth stack for wireless transmission of digitized raw sensor signals to computing device - bar code scanner for acquiring card info - internal electronic reader self-test circuit 2 - The computing device comprising a PDA - microprocessor - memory - color LCD display - keyboard - i/o for communicating test results to other devices - software to control the test and calculate analytical values from raw sensor signals - battery operated with rechargeable batteries via plug in plug-in power supply	- MUX - A/D - wire transmission of digitized raw sensor signals to computing subsystem in same housing - n/a - internal and external electronic reader self-test circuit - microprocessor - memory - monochrome LCD display - keyboard - i/o for communicating test results to other devices - software to control the test and calculate analytical values from raw sensor signals - battery operated with rechargeable batteries via external power supply in downloader cradle	same same different different different same same different same same same same
Measurement temperature	37°C	37°C	same
Measurement sequence	Calibrate test card-introduce sample-measure	Introduce sample-calibrate test cartridge-measure	different
Measurement time	35sec from sample introduction	200 sec from sample introduction	different
Error detection	iQC system to detect user errors iQC system for reader self-check iQC system to detect card non-conformance	iQC system to detect user errors iQC system for reader self-check iQC system to detect card non-conformance	same same same

Figure 5.1 – Table - Comparing epoc Device Performance Characteristics With Predicate Device

The epoc System has the same intended use and utilizes the same test methodologies as the predicate device. Most of the system components are very similar to the predicate device. Differences between the epoc device and the predicate device have no significant effect on the safety or effectiveness of the system.

5.5 Summary of Non-Clinical Test Performance in Support of Substantial Equivalence

5.5.1 Aqueous precision

Experiments were performed in-house to demonstrate the precision of the epoc test methods. The table below shows the results of a twenty day precision study using performed on 4 lots using aqueous controls at two levels L1 and L3 for the blood gases, electrolytes and metabolytes.

Lactate mM	All	
	L1	L3
N	320	320
Mean	7.99	0.94
SWD	0.39	0.03
SDD	0.32	0.03
ST	0.51	0.04
WD CV%	4.9%	3.1%
Total CV%	6.3%	4.7%

Figure 5.2 – Table – 20 Day Precision Study Data

5.5.2 Linearity/Reportable Range

This study was performed in-house using blood samples as per CLSI EP6-A recommendations for evaluation of linearity. A total of nine blood samples were prepared starting with two pools of blood, which were evaluated versus an in-house standard method with traceability to NIST standards. Regression analysis was performed as per CLSI EP6-A. The summary is given in the table in Figure 5.3.

Test Range	Slope	Intercept	R^2
0.3 - 20.1 mM	1.001	0.271	0.999

Figure 5.3 – Table - In House Whole Blood Linearity

5.5.3 Traceability

The epoc System is calibrated is against methods traceable to NIST standards.

The epoc System's test card comprises an on-board calibration material, prepared gravimetrically and assayed on reference systems calibrated with traceability to NIST standards.

Calibration verification uses commercially available calibration verification fluids whose concentration values are traceable to NIST standards.

Quality control materials are commercially available fluids with concentrations traceable to NIST standards.

5.5.4 Detection Limit

This study was performed in-house as per CLSI EP6-A recommendations for evaluation limits of detection and quantification. The low end of the reportable range for the EPOC lactate test (0.30 mM) is greater than or equal to the limit of detection and is statistically discernable from the limit of blank (0.21 mM).

5.5.5 Analytical Specificity

Interference testing4 was performed in-house on the epoc lactate sensor. In each of these tests a pooled human serum was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The lactate bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Unacceptable interference bias was defined as producing a significant error more than 5% of the time.
Significant interfering substances are itemized below:

- Acetaminophen will have no significant effect up to 0.81 mM after which it will increase the lactate reading up to 306 µM/mM Tylenol. Because the therapeutic upper limit for acetaminophen is 0.20 mM, interfering levels of acetaminophen should only be encountered in overdose situations
- Iodide will decrease the lactate reading up to -1.2mM/mM of Iodide up to an Iodide concentration of 0.67 mM. Above 0.67 mM Iodide the decrease will be -1.2mM.
- Bromide will have no significant effect up to 25.4 mM after which it will decrease the lactate reading up to 14.6 µM/mM Bromide.
- Thiocyanate will have no significant effect up to 2.7 mM after which it will decrease the lactate reading by up to 96.6 µM/mM thiocyanate.
- N-Acetylcysteine will have no significant effect up to 3.7 mM after which it will decrease the lactate reading by up to 96.3 µM/mM N-Acetylcysteine.

Ethylene glycol ingestion and metabolism has been shown to produce falsely elevated lactate measurements*. Ethylene glycol plus three metabolism products - Glycolic Acid, Glyoxylic Acid and Oxalic Acid - were tested for interference. Ethylene Glycol and Oxalic Acid do not interfere significantly.

- Glycolic Acid will have no significant effect up to 0.87 mM after which it will increase the lactate reading up to 142 µM/mM glycolic acid.
- Glyoxylic Acid will have no significant effect up to 0.85 mM after which it will increase the lactate reading up to 373 µM/mM glyoxylic acid.

* CMAJ, April 10, 2007, 176(8), p.1097 "Falsely elevated point-of-care lactate measurement after ingestion of ethylene glycol"
The following levels of exogenous interferences were tested and found to be insignificant: 1.66mM (25mg/dL) acetaminophen, 630µmol/L (12.5mg/dL) Na ascorbate, 20mmol/L (588 mg/dL) citrate, 100 µmol/L (~2mg/dL) L-dopa, 9mmol/L (263mg/dL) EDTA, 4.84mmol/L (30mg/dL) ethylene glycol, 105 µmmol/L (0.441mg/dL) Na fluoride, 71 µmol/L Methyldopa, 2.55mmol/L oxidized glutathione, 2.55mmol/L reduced glutathione, 132 µmol/L (1.0mg/dL) hydroxyurea, 292µmol/L (4mg/dL) isoniazide (nydrazid), 81 µmol/L (1.5 mg/dL) K Oxalate, 0.037 mmol/L (1.2 mg/dL) Quinidine.

The following levels of endogenous interferences were tested and found to be insignificant: +342µmol/L (+29.0mg/dL) bilirubin conjugated, +342 µmol/L (+20.1mg/dL) bilirubin unconjugated, +13mmol/L (+503.1mg/dL) cholesterol, +1500µmol/L (+18mg/dL) L-cysteine, +0.8% lipids, pH (+0.4, -0.4), 3% to 10% total protein, 1.4 mM (+ 23.5 mg/dL) Uric Acid.

Low hematocrit did not interfere down to a level of 21 % hematocrit and high hematocrit did not interfere up to a level of 61 % hematocrit.
Triglycerides did not show significant interference up to a level of 37 mM (1430 mg/dL).

5.6 Summary of Clinical Tests Submitted in Support of Substantial Equivalence

5.6.1 Method comparison with Predicate Device

The method comparison studies were performed in field trials at several hospitals on patient samples of whole blood at various locations. Patient specimens were venous, arterial and capillary. The method comparison was against the predicate device.

epoc Lactate vs. i-STAT	
N	373
Sxx	0.215
Syy	0.530
intercept	0.132
slope	0.967
Syx	0.948
X min	0.48
X max	19.95
R^2	0.9711

Figure 5.6 – Table of Method Comparison Summary against Predicate Device

5.6.2 Blood Precision

Blood precision studies were performed in field trials at two (2) hospitals on volunteer samples of whole blood by potential end users. One (1) sample was obtained and tested fresh (WB L2). Another sample was obtained and held for several hours to increase lactate concentration (WB L1). This sample was introduced via epoc Care-Fill Capillary Tubes.

Site 1

User	QC Level	N	Avg	SD	%CV	lot
Phlebotomist 1	WB L1	15	10.24	0.62	6.0%	09231/09230
Phlebotomist 2	WB L1	15	10.27	0.34	3.3%	09231/09230

Figure 5.7 – Table – Blood Precision Study Summary (Site 1)

Site 2

User	QC Level	N	Avg	SD	%CV	lot
Phlebotomist 1	WB L2	15	2.77	0.07	2.7%	09236
Phlebotomist 2	WB L2	15	2.67	0.12	4.7%	09232

Figure 5.8 – Table – Blood Precision Study Summary (Site 2) - Sample Introduced with Capillary Tubes

5.6.3 Aqueous precision

Aqueous precision studies were performed in field trials by potential end users at two (2) hospitals on commercially available blood gas, electrolytes and metabolites control fluids, L1, L2 and L3 (Eurotrol, The Netherlands).

Site 1

User	QC Level	N	Avg	SD	%CV	lot
RN 1	L3	15	0.95	0.031	3.3%	09229
Anesthesia Tech	L3	15	0.94	0.027	2.9%	09229
RN 2	L2	14	2.88	0.05	1.8%	09229
Resp Therapist	L2	15	2.91	0.08	2.8%	09229

Figure 5.9 – Table – Aqueous Precision Study Summary (Site 1)

Site 2

User	QC Level	N	Avg	SD	%CV	lot
RN 1	L1	15	7.34	0.57	7.8%	09264
RN 2	L1	15	7.45	0.42	5.6%	09265

Figure 5.10 – Table – Aqueous Precision Study Summary (Site 2)

5.6.4 Matrix Effects

The method comparison studies were performed in field trials at several hospitals on patient samples of whole blood at various locations. Patient specimens were venous, arterial and capillary. The method comparison was against the predicate device.

	epoc Lactate vs. i-STAT			
	venous	arterial	capillary	all
N	126	73	174	373
Sxx	0.113	0.116	0.290	0.215
Syy	0.586	0.455	0.517	0.530
intercept	0.211	-0.165	0.257	0.132
slope	0.937	1.032	0.955	0.967
Syx	0.750	0.831	1.062	0.948
X min	0.66	0.57	0.48	0.48
X max	19.88	19.95	19.57	19.95
R^2	0.9769	0.9829	0.9653	0.9711

Figure 5.11 – Table of Method Comparison Summary Against Predicate Device By Sample Matrix Type

	Lactate, mM		
matrix	Decision level	2.2	5.0
venous	Average Bias	0.073	-0.103
	95% Confidence Interval ±	0.165	0.113
arterial	Average Bias	-0.094	-0.004
	95% Confidence Interval ±	0.223	0.162
capillary	Average Bias	0.158	0.031
	95% Confidence Interval ±	0.198	0.142
all	Average Bias	0.061	-0.031
	95% Confidence Interval ±	0.119	0.084

Figure 5.12 – Table of Method Comparison Summary Against Predicate Device – Consolidated Bias by Sample Matrix Type

5.6.4.1 Effect of Anticoagulant

The effect of anticoagulant was evaluated on patient samples that were collected using heparinized and non-heparinized collection devices. This study was performed at various POC sites of a hospital (43 samples) and supplemented with in-house studies (17 samples). The data was analyzed using EP9-2A methodology.

epoc Lactate No heparin vs. Heparinized	
N	60
Sxx	0.091
Syy	0.160
intercept	-0.045
slope	1.036
Syx	0.232
X min	0.52
X max	11.21
R^2	0.9916

Figure 5.13 – Table of Heparinized Versus Non-Heparinized Samples

5.7 Summary of Conclusions Drawn from Non Clinical and Clinical Tests

We conclude from the data presented in section 5.5 that the device performs effectively. We conclude from the data section 5.6 that the clinical performance of the device is equivalent to the predicate device: i-Stat Model 300 Portable Clinical Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Epocal, Inc.
c/o Mr. Roy Layer
Director of Quality Assurance
and Regulatory Affairs
2060 Walkley Road
Ottawa, Ontario Canada K1G-3P5

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUN 09 2010

Re: k093297
Trade Name: epoc Lactate test
Regulation Number: 21 CFR §862.1450
Regulation Name: Lactic acid test system.
Regulatory Class: Class I, meets limitations of exemptions, 21 CFR §862.9 (c)(9)
Product Codes: KHP
Dated: May 13, 2010
Received: May 17, 2010

Dear Mr. Layer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k093297

Device Name: epoc Lactate test

Indication For Use:

The Lactate test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Lactate measurements from the epoc Blood Analysis System are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k093297